#20 Appeal Brief S. Byce 1/28/03

IN THE UNITED STATES PATENT & TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	Group Art Unit: 3763
MIDDLEMAN et al.	Examiner: Cris Rodriguez
Serial No.: 09/123,614	
Filed: June 28, 1998	
For: DEVICE FOR ANCHORING TUBULAR ELEMENT	Pasadena, California

APPELLANTS' BRIEF

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Elaine Porter

Dear Sir:

This is an appeal from the final rejection dated July 16, 2002, of the claims in the above-referenced application.

1. REAL PARTY IN INTEREST

The real party in interest is the assignee of the application, Medtronic, Inc.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences presently pending that are known to Appellants or Appellants' attorney.

3. STATUS OF THE CLAIMS

Claims 1, 2, 7-11, 22 and 24-47 are pending in the application. All of the claims have been rejected. The rejections of all of the claims have been appealed.

4. STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendments were filed after the final Office Action of July 16, 2002. However, claim 28 was erroneously submitted in the Amendment filed on March 26, 2001. As explained in the remarks of the Amendment filed on March 26, 2001, on page 8, Appellants intention was to amend claim 28 only to change "deployment means" to "deployment element". Moreover, claims 29 to 31 were inadvertently omitted from the Amendment filed on March 26, 2001. As seen from the Amendment of March 26, 2001, there was no intention to cancel claims 29 to 31. Therefore, a correct amended claim 28 as well as claims 29 to 31 are found in Attachment A to the Appendix.

5. SUMMARY OF THE INVENTION

The invention relates to an apparatus for anchoring a tubular element, such as a catheter, within a passageway in a mammalian body. In particular, the present invention relates to an anchoring device provided within a catheter that is operable to position and retain a tubular element in place within vessels, arteries, ducts, and channels within the mammalian body.[1] The apparatus comprises a tubular element, preferably a catheter, having a flexible, elongated, hollow tubular outer lumen with a central longitudinal axis extending through it.[2]

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[1]Citations to the application will be in the form "page:lines" throughout. *See,* 2:2-5.

[2]*See*, elements 20, 22 Fig. 1 and 11:16-18.

The outer lumen has a proximal end and a distal end.[3] The apparatus further comprises deployment means positioned within the outer lumen and slidable with respect to the outer lumen.[4] The deployment means has a proximal end and a distal end and an elongated bore extending between the proximal end and the distal end.[5] Because the deployment means is hollow, liquids may be transported through the bore to the passageway site and devices, such as a transducer, may be inserted and used at the site.[6]

The apparatus further comprises a plurality of resilient anchoring members coupled to the distal end of the deployment means and extending longitudinally beyond the distal end of the deployment means.[7] Each anchoring member is reversibly movable by the deployment means between a first position and a second position.[8] In the first position, at least a portion of each anchoring member is retracted within the outer lumen of the tubular element. In the second position at least a portion of each anchoring member is deployed exteriorly to the outer lumen of the tubular element, so as to engage an inner wall of the mammalian passageway and anchor the tubular element in a selected position within the passageway.[9]

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[3]*See*, elements 24, 26 Fig. 1 and 10:16-19.

[4]*See*, element 30 Fig. 1 and 11:7-10.

[5]*See*, elements 38, 40, 42 Fig. 1 and 11:11-14.

[6]*See*, 11:14-16.

[7]*See*, element 56 Fig. 1 and 12:12-14.

[8]*See*, 18:18 to 19:3 and 5:20-21.

[9]*See,* 5:21 to 6:3 and 19:9-13.

The apparatus is particularly helpful for anchoring and retaining steerable catheters within blood vessels, stabilizing blood flow sensors accurately in the center of a blood vessel to obtain an accurate flow or sensor reading, minimizing the movement of transluminal ultrasonic sensors to obtain high quality images, and minimizing the movement of tubular components used in connection with drug delivery systems, ultrasound systems, and body sampling systems. Additionally, the present invention is easy to manufacture and assemble, requires no power supply, requires no heating or cooling down, and minimizes the potential for tissue damage or discomfort to a patient upon insertion, deployment and removal of the device.[10]

6. ISSUES PRESENTED

The first issue presented is whether or not the Examiner properly rejected claim 1 under 35 U.S.C. § 102(b) as allegedly being anticipated by Cathcart et al. (U.S. Patent No. 5,681,347).

The second issue presented is whether or not the Examiner properly rejected claim 1 under 35 U.S.C. § 102(b) as allegedly being anticipated by Goldberg et al. (U.S. Patent No. 5,152,777).

The third issue presented is whether or not the Examiner properly rejected claim 38 under 35 U.S.C. § 102(e) as allegedly being anticipated by Hayashi (U.S. Patent No. 5,910,144).

The fourth issue presented is whether or not the Examiner properly rejected claim 28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goldberg et al. (U.S. Patent

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[10]*See*, 5:4-11.

No. 5,152,777) in view of Hayashi (U.S. Patent No. 5,910,144).

7. GROUPING OF CLAIMS

Appellants do not consider all of the claims of this application to stand and fall together.

Specifically, Appellants consider this application to contain three separately patentable groups of claims as follows:

Group I: 1, 2, 7 to 11, 22, 24 to 27;

Group II: 28 to 37; and

Group III: 38 to 47.

Groups I, II, and III stand separately from each other because each group has an independent claim separately rejected by the Examiner under different prior art as explained further below.

The claims are attached as Exhibit A to the Appendix.

8. ARGUMENT

Legal Standard For Anticipation Under 35 U.S.C. §§102(b) and102(e)

Anticipation under 35 U.S.C. §102 is only established if (1) all elements of an invention, as stated in a patent claim, (2) are identically set forth, (3) in a single prior art reference. Gechter v. Davidson, 116 F.3d 1154, 1157; 43 USPQ2d 1030, 1032 (Fed. Cir. 1997).

Legal Standard For Obviousness Under 35 U.S.C. §103(a)

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference or references, when combined, must teach or suggest all the claim limitations. M.P.E.P. 706.02(j), citing, In re Vaeck, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991). Additionally, the teaching or suggestion to make the claimed invention must be found in the prior art and not based on applicant's disclosure. MPEP § 2141.01(III), MPEP § 2144(XA).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." M.P.E.P. 706.02(j), citing, Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

A. Claim 1 is not anticipated under 35 U.S.C. § 102(b) by Cathcart et al. (U.S. Patent No. 5,681,347).

Claims 1 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cathcart et al. (U.S. Patent No. 5,681,347). In the final rejection, the Examiner contends that Cathcart et al. discloses a device 10 comprising a tubular element 13 comprising a hollow tubular lumen, a deployment element 17, and a plurality of resilient anchoring members 24 attached to the distal end of the inner lumen as claimed. The Examiner states the that word

"attached" means to join or connect. The Examiner then goes on to state that the word "join" is being used as "to put into close association or relationship" according to the Webster's II Dictionary.

Appellants submit that the Examiner's rejection is fatally defective, because Cathcart et al. does not teach or suggest the limitation of claim 1 of "a plurality of resilient anchoring members attached to the distal end of the inner lumen." Words in claims are to be given their ordinary meaning in the absence of indication in the application to the contrary. Gentex Corp v. Donnelly Corp., 69 F.3d 527, 530, 36 USPQ2d 1667, 1669 (Fed. Cir. 1995). Courts frequently look to dictionaries to determine ordinary meaning. Sage Products Inc. v. Devon Industries, Inc., 126 F.3d 1420, 1430-1431, 44 USPQ2d 1103, 1113 (Fed. Cir. 1997). Appellants respectfully submit that the ordinary meaning of "attach" is "to cause to adhere; to tie, bind or fasten; as to attach one thing to another by a string, by glue, etc." as defined in the Webster's New Twentieth Century Dictionary, 2nd Ed., ©1983 by Simon and Schuster, New York, New York, 10020.

The ordinary meaning submitted by Appellants is consistent with the specification which states on page 16, line 16 to page 17, line 8, that the anchoring members may be attached to the deployment means by various methods known in the art, depending on what material the anchoring members and deployment means are comprised of. Listed methods to create attachment to the deployment means include welding, soldering press-fitting, crimping, swedging, epoxy, laser welding and mounting. The attachment of the anchoring means to the distal end of the inner lumen allows the resilient anchoring members to be reversibly moveable

by the deployment element.

Cathcart et al. teaches a catheter for deploying a vena cava filter. As seen from Figs. 2, 4, and 5 and from the specification at Col. 5, line 57 to Col. 6, line 2 of Cathcart et al.,

> a cup shaped portion 21 engages a proximal end 22 of a device 23, such as a vena cava filter, having radially extending penetrating or hook portions 24 disposed within the inner portion of the metal segment 20. . . Displacement of the inner member 17 distally relative to the outer member 13 moves the cup shaped portion 21 from the first position depicted in FIG. 3 through a second position depicted in FIG. 4 to a third position depicted in FIG. 5 in which the cup shaped portion 21 distally extends beyond the distal end 15 of the filter 23 and deploys in a patient's lumen.

If the device 23 were attached to cup shaped portion 21, then the device 23 could not deploy in a patent's lumen. Thus, although the device 23 engages the cup shaped portion 21, the device, and its "extending penetrating or hook portions 24" are not "attached to the distal end of the inner lumen" as required by claim 1.

Moreover, Appellants submit that Cathcart et al. does not teach or suggest the limitation of claim 1 that "each anchoring member [is] reversibly moveable by the deployment element between a first position and a second position." As explained above, the penetrating or hook portions 24 taught by Cathcart et al. are part of a deployable device 23. Cathcart et al. does not provide a means for pulling the deployable device 23 back inside of the catheter once deployed. Thus, Cathcart et al. does not teach or suggest all of the limitations of claim 1.

Cathcart et al. is directed to a catheter for deploying a vena cava filter, not to anchoring a catheter within a passageway formed in a mammalian body to perform measurements. Appellants respectfully submit that one skilled in the art would have no motivation to modify Cathcart et al. to teach the limitations of claim 1 that "a plurality of resilient anchoring

members [are] attached to the distal end of the inner lumen" and "each anchoring member [is] reversibly moveable by the deployment element between a first position and a second position."

Therefore, Appellants respectfully submit that claim 1 is novel and nonobvious over Cathcart et al. Claims 2, 7 to 11, 22, and 24 to 27 depend from claim 1 and by definition contain all of the limitations of claim 1. Therefore, claims 2, 7 to 11, 22, and 24 to 27 are patentable over Cathcart et al. for the same reasons that claim 1 is patentable over Cathcart et al.

B. Claim 1 is not anticipated under 35 U.S.C. § 102(b) by Goldberg et al. (U.S. Patent No. 5,152,777).

Claims 1 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Goldberg et al. (U.S. Patent No. 5,152,777). Specifically, the Examiner alleges that Goldberg discloses a device having a tubular element 70, 72, 74 with a hollow tubular lumen, a deployment element 60, 90, 92, and a plurality of resilient anchoring members 32a-f as claimed.

Appellants submit that the Examiner's rejection is fatally defective, because Goldberg et al. does not teach or suggest the limitation of claim 1 that the deployment element has an inner lumen, and that "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end." As explained above, the inner lumen of the deployment element allows liquids to be transported through the bore to the passageway site, and devices, such as a transducer, to be inserted and used at the site.

Like Cathcart et al., Goldberg et al. is directed to a blood vessel filter (trap) delivery system. Like Cathcart et al., there is nothing in Goldberg et al., that addresses the problem of how to anchor a sensing device at a specific location within a passageway of a mammalian patient. Goldberg et al. does not teach or suggest an anchoring system using an inner lumen having a bore extending completely through the inner lumen from the proximal end to the distal end.

As explained in Col. 7, lines 43 to 63 of Goldberg et al., the trap has a stem 60; the stem 60 has a proximal end 90. To introduce the trap to the appropriate location, the proximal end of the stem is threaded onto an extension stem 92. The trap, stem and extension stem are drawn into an introducer/remover apparatus. Appellants submit that the extension stem 92 is part of the deployment device. As explained at Col. 7, lines 53-56 and shown in Fig. 5A, the trap stem 90 is threaded at 94 to receive trap extension stem 92 having mating threaded end 96. Appellants respectfully submit that the innermost passageway is blocked at the junction of elements 94 and 96. Therefore, Goldberg does not teach or suggest a deployment element having "a bore extending completely through the inner lumen from the proximal end to the distal end".

As explained above, Goldberg et al. is directed to a catheter for deploying a filter, not to anchoring a catheter within a passageway formed in a mammalian body to perform measurements. Appellants respectfully submit that one skilled in the art would have no motivation to modify Goldberg et al. to teach the limitation of claim 1 that "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal

end."

Thus, Appellants submit that claim 1 is novel and nonobvious over Goldberg et al. Claims 2, 7 to 11, 22, and 24 to 27 all depend from claim 1 and by definition contain all of the limitations of claim 1. Therefore, claims 2, 7 to 11, 22, and 24 to 27 are patentable over Goldberg et al. for the same reason that claim 1 is patentable over Goldberg et al.

C. **Claim 38 is not anticipated under 35 U.S.C. § 102(e) by Hayashi (U.S. Patent No. 5,910,144).**

Independent claim 38 stands rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Hayashi (U.S. Patent No. 5,910,144). Specifically, the Examiner states that Hayashi discloses a prosthesis gripping system comprising a tubular element 20, 26 comprising a hollow tubular lumen, a deployment element 50, and a plurality of resilient anchoring members 40 as claimed. Appellants submit that the Examiner's rejection is fatally defective, because Hayashi does not teach or suggest the limitation of claim 38 that the deployment element has an inner lumen and that, "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end."

The Hayashi reference teaches a prosthesis gripping system for enabling the manipulation of a prosthesis deployed or implanted at a repair site.[11] As is the case with the Cathcart et al. and the Goldberg et al. references, the Hayashi reference is not directed to the problem of how to locate a sensor at a specific location within the passageway of a mammalian patient. Therefore, it is not surprising that Hayashi fails to teach the use of an inner lumen

[11] *See*, Hayashi, Col. 3, lines 34-38.

having "a bore extending completely through the inner lumen from the proximal end to the distal end."

Hayashi teaches a tubular element 20, 26 having a channel 24.[12] Appellants submit that the channel 24 corresponds to the hollow tubular outer lumen in claim 38. A wire 36 extends through the channel 24.[13] In one embodiment of Hayashi, elements 40 for gripping a prosthesis are attached directly to the end of the wire.[14] In another embodiment of Hayashi a tube 50 is secured to the distal end of the wire, and extends about the secured ends 42 of elements 40 to crimp the joint between wire 36 and secured ends of elements 40.[15] Appellants respectfully submit that the wire is the deployment means and that the wire does not have a bore. Appellants also respectfully submit that even if the tube 50 is considered to be the deployment means, the crimping of the tube 50 to form the joint between the wire 36 and the secured ends 42 of elements 40 necessarily closes off the proximal end of the tube 50.

Accordingly, Hayashi fails to teach or suggest the use of an inner lumen having "a bore extending completely through the inner lumen from the proximal end to the distal end." Thus, Hayashi does not teach or suggest all of the limitations of claim 38.

As explained above, Hayashi is directed to a prosthesis gripping system for enabling the manipulation of a prosthesis deployed or implanted at a repair site, not to anchoring a catheter

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[12]*See*, Hayashi, Col. 3, lines 59-63.

[13]*See*, Hayashi, Col. 4, lines 4-7.

[14]*See*, Hayashi, Col. 4, lines 11-14.

[15]*See*, Hayashi, Col. 4, lines 26-29.

within a passageway formed in a mammalian body to perform measurements. Appellants respectfully submit that one skilled in the art would have no motivation to modify Hayashi to teach the limitation of claim 38 that "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end."

Thus, Appellants submit that claim 38 is novel and nonobvious over Hayashi. Claims 39 to 47 all depend from claim 38 and by definition contain all of the limitations of claim 38. Therefore, claims 39 to 47 are patentable over Hayashi for the same reason that claim 38 is patentable over Hayashi.

D. Claim 28 is not obvious under 35 U.S.C. § 103(a) over Goldberg in view of Hayashi.

Independent claim 28 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goldberg et al. in view of Hayashi. Specifically, the Examiner alleges that Goldberg discloses a device having a tubular element 70, 72, 74 with a hollow tubular lumen, a deployment element 60, 90, 92, and a plurality of resilient anchoring members 32a-32f as claimed. However, the Examiner states that Goldberg fails to disclose the anchoring members being attached within the wall of the deployment element inner lumen, or attached to the inner surface of the wall of the deployment element inner lumen, and the anchoring members having a substantially oval cross section. The Examiner cites to Hayashi for teaching anchoring members 40 being attached to the inner surface of the wall of the deployment element 50 inner lumen. The Examiner concludes that it would have been obvious to modify Goldberg et al. by attaching the anchoring members to the inner surface of the wall of the deployment element

inner lumen as taught by Hayashi. The Examiner further states that the oval cross section is an obvious variation from the circular cross section. Appellants submit that the Examiner has not made a prima facie case of obviousness, because Goldberg et al. and Hayashi either alone or in combination do not teach all of the limitations of claim 28.

Claim 28 recites the limitation that the deployment element comprises a hollow tubular inner lumen, the inner lumen having a proximal end and a distal end, and "a bore extending completely through the inner lumen from the proximal end to the distal end." As explained above in sections 8B and 8C, both Goldberg et al. and Hayashi fail to teach or suggest this limitation. Therefore, Appellants submit that claim 28 is patentable over Goldberg et al. in view of Hayashi. Claims 29 to 37 depend from claim 28 and by definition contain all of the limitations of claim 28. Therefore, claims 29 to 37 are patentable over Goldberg et al. and Hayashi for the same reasons as claim 28.

9. CONCLUSION

As explained above, each of the Examiner's rejections fails. Issuance of a notice of allowance is therefore appropriate and respectfully requested.

Respectfully Submitted,

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APPENDIX

Exhibit A: Claims on Appeal

1. An apparatus for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having a wall with an inner surface, the apparatus comprising:

a) a tubular element comprising a hollow tubular outer lumen having a proximal end and a distal end;

b) a deployment element positioned within the outer lumen and slidable with respect to the outer lumen, the deployment element comprising a hollow tubular inner lumen with a wall having an inner surface, where the inner lumen has a proximal end and a distal end, and where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end; and,

c) a plurality of resilient anchoring members attached to the distal end of the inner lumen and extending longitudinally beyond the distal end of the inner lumen, each anchoring member being reversibly movable by the deployment element between a first position and a second position, where in the first position, at least a portion of each anchoring member is retracted within the outer lumen, and where in the second position, at least a portion of each anchoring member is deployed exteriorly to the outer lumen, so as to engage the inner surface of the mammalian passageway and anchor the tubular element in the passageway.

2. The apparatus of claim 1, where the tubular element is a catheter.

7. The apparatus of claim 1, where the deployment element further comprises a guide

wire having a proximal end and a distal end, and where the inner lumen is a collar member attached to the distal end of the guide wire.

8. The apparatus of claim 1, where the anchoring members comprise a pseudoelastic material.

9. The apparatus of claim 8, where the pseudoelastic material is a nickel titanium alloy.

10. The apparatus of claim 1, where the anchoring members comprise spring steel.

11. The apparatus of claim 1, where the plurality of resilient anchoring members comprises two anchoring members.

22. A method for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having an inner surface, the method comprising:

a) providing the apparatus of claim 1;

b) positioning the apparatus at a selected location within the passageway; and

c) deploying at least a portion of anchoring members against the inner surface of the passageway thereby anchoring the tubular element within the passageway at the selected location.

24. The apparatus of claim 1, where the anchoring members are attached within the wall of the inner lumen.

25. The apparatus of claim 1, where the anchoring members are attached to the inner surface of the wall of the inner lumen.

26. The apparatus of claim 1, where the anchoring members are substantially oval in

cross-section.

27. The apparatus of claim 1, where the anchoring members have a top portion and the top portion is substantially flat.

28. An apparatus for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having a wall with an inner surface, the apparatus comprising:

a) a tubular element comprising a hollow tubular outer lumen having a proximal end and a distal end;

b) a deployment element positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means comprising a hollow tubular inner lumen with a wall having an inner surface, where the inner lumen has a proximal end and a distal end, and where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end; and,

c) a plurality of resilient anchoring members attached within the wall of the inner lumen and extending longitudinally beyond the distal end of the inner lumen, each anchoring member being reversibly movable by the deployment means between a first position and a second position, where in the first position, at least a portion of each anchoring member is retracted within the outer lumen, and where in the second position, at least a portion of each anchoring member is deployed exteriorly to the outer lumen, so as to engage the inner surface of the

mammalian passageway and anchor the tubular element in the passageway.[1]

29. The apparatus of claim 28, where the tubular element is a catheter.[2]

30. The apparatus of claim 28, where the deployment means further comprises a guide wire having a proximal end and a distal end, and where the inner lumen is a collar member attached to the distal end of the guide wire.[3]

31. The apparatus of claim 28, where the anchoring members comprise a pseudoelastic material.[4]

32. The apparatus of claim 31, where the pseudoelastic material is a nickel titanium alloy.

33. The apparatus of claim 28, where the anchoring members comprise spring steel.

34. The apparatus of claim 28, where the plurality of resilient anchoring members comprises two anchoring members.

35. A method for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having an inner surface, the method comprising:

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[1]This claim was erroneously submitted in the amendment of March 26, 2001. As explained in the remarks of the amendment of March 26, 2001, on page 8, Appelant's intention was to amend claim 28 only to change "deployment means" to "deployment element".

[2]This claim was erroneously omitted in the Amendment of March 26, 2001. As seen from the amendment, there was no intention to cancel this claim.

[3]This claim was erroneously omitted in the Amendment of March 26, 2001. As seen from the amendment, there was no intention to cancel this claim.

[4]This claim was erroneously omitted in the Amendment of March 26, 2001. As seen from the amendment, there was no intention to cancel this claim.

a) providing the apparatus of claim 28;

b) positioning the apparatus at a selected location within the passageway; and

c) deploying at least a portion of anchoring members against the inner surface of the passageway thereby anchoring the tubular element within the passageway at the selected location.

36. The apparatus of claim 28, where the anchoring members are substantially oval in cross-section.

37. The apparatus of claim 28, where the anchoring members have a top portion and the top portion is substantially flat.

38. An apparatus for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having a wall with an inner surface, the apparatus comprising:

a) a tubular element comprising a hollow tubular outer lumen having a proximal end and a distal end;

b) a deployment element positioned within the outer lumen and slidable with respect to the outer lumen, the deployment element comprising a hollow tubular inner lumen with a wall having an inner surface, where the inner lumen has a proximal end and a distal end, and where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end; and,

c) a plurality of resilient anchoring members attached to the inner surface of the wall of the inner lumen and extending longitudinally beyond the distal end of the inner lumen, each

anchoring member being reversibly movable by the deployment element between a first position and a second position, where in the first position, at least a portion of each anchoring member is retracted within the outer lumen, and where in the second position, at least a portion of each anchoring member is deployed exteriorly to the outer lumen, so as to engage the inner surface of the mammalian passageway and anchor the tubular element in the passageway.

39. The apparatus of claim 38, where the tubular element is a catheter.

40. The apparatus of claim 38, where the deployment element further comprises a guide wire having a proximal end and a distal end, and where the inner lumen is a collar member attached to the distal end of the guide wire.

41. The apparatus of claim 38, where the anchoring members comprise a pseudoelastic material.

42. The apparatus of claim 41, where the pseudoelastic material is a nickel titanium alloy.

43. The apparatus of claim 38, where the anchoring members comprise spring steel.

44. The apparatus of claim 38, where the plurality of resilient anchoring members comprises two anchoring members.

45. A method for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having an inner surface, the method comprising:

a) providing the apparatus of claim 38;

b) positioning the apparatus at a selected location within the passageway; and

c) deploying at least a portion of anchoring members against the inner surface of the

passageway thereby anchoring the tubular element within the passageway at the selected location.

46. The apparatus of claim 38, where the anchoring members are substantially oval in cross-section.

47. The apparatus of claim 38, where the anchoring members have a top portion and the top portion is substantially flat.